Effective Date: 7/1/2017
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C4220-A

Fentanyl Patch

PRODUCTS AFFECTED

Duragesic (fentanyl) patch

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Chronic, severe pain in opioid tolerant patients

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policywas approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. CHRONIC, SEVERE NON-CANCER PAIN:
1. Member has a diagnosis of severe pain AND the same source of pain is chronic (≥ 6 months) in nature
AND
2. Documentation member is opioid-tolerant and requires around-the clock-long-term opioid treatment.
AND
3. The member does NOT have any FDA labeled contraindications to requested drug
AND

4. Prescriber attestation that non-pharmacologic therapy (e.g. physical therapy, exercise, Cognitive Behavioral Therapy, weight loss) and non-opioid therapy (e.g. topical diclofenac, nonsteroidal anti-inflammatory drugs (NSAIDs), tricyclic antidepressants (TCAs), and serotonin and norepinephrine reuptake inhibitors (SNRIs), or anticonvulsants) were maximized prior to prescribing opioids or as concurrent therapy
   AND
5. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance ofa prescription or continuation of therapy request
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's recordson a periodic basis or as necessary to ensure no abuse or diversion
   AND
6. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member)
   AND
7. The member can safely be started on the requested dose of fentanyl (i.e., member is opioid tolerant-taking at least 60mg per day of morphine milligram equivalents for at least one week)
   AND
8. Prescriber attests that member has a treatment plan or other measures to provide a baseline status for stabilization/improvement in the patient. A treatment plan may include: Pain intensity (scales or ratings),Functional status (physical and psychosocial), Patient's goal of therapy (level of pain acceptable and/or functional status), and current non- pharmacological treatment
   AND
9. Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failureor documented intolerance to ONE formulary ORAL immediate acting products
   AND
10. FOR DOSING REQUESTS GREATER THAN MED LIMIT (PER STATE/LOB): Documentation that prescriber has discussed the high dose with the patient, provides a therapeutic clinical rational for a dose higher than the maximum allowed MED, an appropriate titration schedule to the current dose andplan for maintenance dosing once goals are reached.

B. ACTIVE TREATMENT OF CANCER RELATED PAIN:
1. Documentation of cancer diagnosis and need for pain therapy
   AND
2. Documentation that the member had an adequate trial and therapeutic failure or documented intolerance to ONE formulary ORAL immediate acting products

CONTINUATION OF THERAPY:

A. CHRONIC, SEVERE PAIN:
1. Documentation of updated treatment plan within the last 6 months
   AND
2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request
   OR
   (b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion
   AND
3. Prescriber agrees to administer random clinical drug testing a minimum of twice per year (*or more frequently as appropriate for member)

AND

4. Documentation of positive clinical response as demonstrated by improvement or stabilization in pain symptoms and/or pain control.
   AND
5. FOR DOSING REQUESTS GREATER THAN MED LIMIT (PER STATE/LOB):
   i. Dose requested is titrated down from initial authorization. If not, the prescriber has explained medical necessity for continued dosing above maximum state/line of business MME: (i) A treatment plan that includes a proposed regimen for reducing the dose of opioid or a reason is given why a dose decrease is not recommended for the member. (ii) Documentation of member's response to the requested medication (ex. decreased pain, improved level of functioning or quality of life.)
   AND
   ii. Provider has submitted an attestation that the following risk assessment was performed the WITHIN THE LAST 2 WEEKS: Checked the state's Prescription Monitoring Program/ Prescription Drug Monitoring Program (PMP/PDMP) for opioid over dosages or dangerous combinations, Reviewed a urine drug screen (UDS) or offered a prescription for naloxone to patients or patient's household if member has risk factors of prior overdose, substance use disorder, doses in excess of 90 Morphine Equivalent Dosing (MED)/ day or concomitant benzodiazepines use, For evidence of Substance use Disorder, prescriber will offeror arrange for evidence based treatment where needed
   AND
   iii. Documentation of sustained improvement in Pain or Function (e.g., PEG scale with a 30% response from baseline); if no response, an alteration to the treatment plan has been initiated to discontinue treatment

B. ACTIVE TREATMENT OF CANCER RELATED PAIN:
1. Documentation of positive clinical response as demonstrated by improvement or stabilization in pain symptoms and/or pain control.

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: for up to 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a pain specialist or oncologist [If prescribed in consultation, consultationnotes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:
No restriction

QUANTITY:
10 patches per 30 days
NOTE: For request for quantities above 10 patches/30 days (1 patch every 72 hours)
1. Prescriber to provide documentation that member has failed 72-hour dosing and is experiencing end of dosage pain AND prescriber has evaluated if the member has had patch exposure to heat that could beincreasing the rate of absorption of fentanyl from the transdermal patch

Maximum Quantity Limits – Maximum Quantity is 1 patch every 48 hours
NOTE*Medications with a Morphine Equivalent Dosing (MED) > 200 for those patients without

a diagnosis of cancer, end-of-life or palliative care, will require a medical director Review

PLACE OF ADMINISTRATION:
The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Transdermal

DRUG CLASS:
Opioid Agonists

FDA-APPROVED USES:
The management of pain in opioid-tolerant patients, severe enough to require daily, around-the- clock, long-term opioid treatment and for which alternative treatment options are inadequate

COMPENDIAL APPROVED OFF-LABELED USES: None

APPENDIX

APPENDIX: None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
90 MME/day: 90 mg of hydrocodone (9 tablets of hydrocodone/ acetaminophen 10/325) 60 mg of oxycodone (~2 tablets of oxycodone sustained release 30 mg)
~20 mg of methadone (4 tablets of methadone 5 mg)

APPENDIX:

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

Conditions for Distribution and Use of Methadone Products for The Treatment Of Opioid Addiction Code of Federal Regulations, Title 42, Sec 8 Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards (42 CFR 8.12). See below for important regulatory exceptions to the general requirement for certification to provide opioid agonist treatment. Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of the drug supply, revocation of the program approval, and injunction precluding operation of the program. Regulatory Exceptions To The General Requirement For Certification To Provide Opioid Agonist Treatment: During inpatient care, when the member was admitted for any condition other than concurrent opioid addiction (pursuant to 21CFR 1306.07(c)), to facilitate the treatment of the primary admitting diagnosis). During an emergency period of no longer than 3 days while definitive care for the addiction is being sought in an appropriately licensed facility (pursuant to 21CFR 1306.07(b)).

Note: *Outpatient maintenance and outpatient detoxification treatment may be provided only by Opioid Treatment Programs (OTPs) certified by the Federal Substance Abuse and Mental Health Services Administration (SAMHSA) and registered by the Drug Enforcement Administration (DEA). This does not preclude the maintenance treatment of a member with concurrent opioid addiction who is hospitalized for conditions other than opioid addiction and who requires temporary maintenance during the critical period of his/her stay, or of a member whose enrollment has been verified in a program which has been certified for maintenance treatment with methadone*

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of fentanyl are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off- label policy.

OTHER SPECIAL CONSIDERATIONS:
Food and Drug Administration (FDA) Black Box warning on concomitant use with benzodiazepines: Food and Drug Administration (FDA) black box warning: Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other central nervous system (CNS) depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation and the associated signsand symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other central nervous system (CNS) depressants, including alcohol. www.fda.gov/Drugs/DrugSafety/ucm518473.htm

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Transdermal system: 12 mcg/hour, 25 mcg/hour, 37.5mcg/hour, 50 mcg/hour,62.5mcg/hour, 75 mcg/hour, 87.5mcg/hour, 100 mcg/hour

REFERENCES

1. Duragesic (fentanyl) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; March 2021.
2. Fentanyl transdermal patch [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc; November 2019.
3. Fentanyl transdermal system [prescribing information]. Caldwell, NJ: LTS Lohmann Therapy Systems Corp;August 2021.
4. Centers for Disease Control and Prevention. 2018 Annual Surveillance Report of Drug-Related Risks and Outcomes — United States. Surveillance Special Report 2. Centers forDisease Control and Prevention, U.S.Department of Health and Human Services. Published August 31, 2018.
5. Centers for Disease Control and Prevention. Calculating Total Daily Dose of Opioids forSafer Dosage. Centersfor Disease Control and Prevention, U.S. Department of Health and Human Services. Published